The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

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→ Dr. V. Cracknell

Dear Susanne

Subject: VICH Topic GL9, GCP Guideline

At the end of the consultation period for these guidelines the EU only has received comments from Sweden, a copy of which is enclosed for forwarding to the Chairman, Dr Cracknell.

Kind regards

Yours sincerely

Peter G.H. Jones
Head of Unit

cc Dr C Verschueren

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LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

31 May 1999 587:1999/349

EMEA
Secretariat Veterinary Unit
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United Kingdom

Re.: VICH Topic GL 9 Guideline on Good Clinical Practice (EMEA/CVMP /595/98-CONSULTATION)

In response to the circulation of the above draft Guideline on Good Clinical Practice , the Medical Products Agency has consulted the relevant authorities and interested parties in Sweden.

In general, the content of the guideline is welcomed and endorsed. The Swedish Agricultural Administration has the following comments, which are also endorsed by the Medical Product Agency. The guideline should be supplemented with references to national animal welfare legislation. The use, breeding and keeping of test animals and other animals are regulated in national law which is based on the Conventions of the Council of Europe as well as the Directives of the European Union. It is therefore suggested to introduce the following sentences under respective paragraph.

Paragraph 6.3.11 and 6.3.15 should be supplemented as follows: The animals must be kept and used in accordance with the national animal welfare legislation.

Paragraph 6.3.11.3 should be supplemented as follows: The climate must be adapted for the animals, which are kept in animal facilities. Climatic factors of significance to the animals should be described.

Paragraph 6.3.12.2 should be changed as follows: Provide total composition of the feed (feed materials, vitamins and other feed additives) and calculated nutrient densities for all feeds used in the study.

Two minor editorial comments were also put forward. See enclosed copies.

On behalf of the Medical Products Agency

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2.4. Each individual involved in conducting a clinical study should be qualified by education, training, and expertise to perform ~~their~~ his/her respective task(s). These individuals should demonstrate, in a manner that is evident from the study documentation, the highest possible degree of professionalism in the recording and reporting of study observations.

2.5. The relevant regulatory authority should provide procedures which independently assure that the study animals and the human and animal food chains are protected. The relevant regulatory authority should also assure that the requirement for obtaining informed consent from the owner of the animals is established and followed.

2.6. Studies covered by Good Laboratory Practice (GLP), basic exploratory studies or other clinical studies not intended to be used for regulatory support are not included in the scope of this guidance. However, data derived from safety and pre-clinical studies may be required to be submitted to the relevant regulatory authority in order that subsequent clinical studies may be properly authorized prior to commencement.

2.7. Wherever possible, investigational veterinary products should be prepared, handled and stored in accordance with the concepts of good manufacturing practice (GMP). Details of preparation, handling and storage of investigational veterinary products should be documented and the products used in accordance with the study protocol.

2.8. The assurance of quality of every aspect of the study is a fundamental component of sound scientific practices. The principles of GCP support the use of quality assurance (QA) procedures for clinical studies. It is perceived that the sponsor would be the party responsible for the QA functions for these studies. All participants in clinical studies are encouraged to adopt and adhere to generally recognized sound QA practices.

3. THE INVESTIGATOR

3.1. General.

3.1.1. The investigator is the individual responsible for all aspects of the conduct of the study. These would include: the dispensing and the administration of the investigational and control veterinary product(s), the implementation of the study protocol, the collection and reporting of the study data and the protection of the health and welfare of the personnel involved in the study and the animals during the study.

3.1.2. If a study is conducted by a group of individuals, the investigator is the leader of the group. An individual should not serve as both the investigator and the monitor of any one study.

6.3.12.1. Determine the nutrient needs of the study animals and prepare feeds meeting these needs.

6.3.12.2. Provide quantitative ingredient lists (feedstuffs, vitamin and mineral premixes and, as appropriate, permissible feed additives) and calculated nutrient densities for all feeds used in the study.

6.3.12.3. Describe procedures for the sampling of the feed used in the study and ~~their~~ subsequent analysis for selected nutrients of these samples

6.3.12.4. Develop and follow objective criteria to determine whether feeds used in the study, based on actual laboratory nutrient analyses, meet the pre-determined calculated requirements.

6.3.12.5. Provide a feeding program (feeding schedule).

6.3.12.6. Collect records of the amount of feed offered and refused.

6.3.13. Investigational veterinary and control product(s).

6.3.13.1. Clearly and precisely identify the investigational veterinary product to readily permit an unambiguous determination of the specific formulation. Instructions for the further mixing (if any), packaging and storage of these products should be stated.

6.3.13.2. If the investigational veterinary product is administered in feed or water, describe the procedures for determining the concentration of the investigational veterinary product in the feed or water, including the sampling methods and assay methodologies (e.g. laboratory used, analytical method, number of replicates, assay limits, permitted analytical variation) to be used. Develop and follow objective criteria to determine whether the investigational veterinary product concentration in the feed or water is adequate.

6.3.13.3. Identify control products by generic or trade name; dosage form, formulation (ingredients); concentration; batch number; expiry date. Store and use these products according to label directions.

6.3.14. Treatments. For the investigational and control veterinary product(s):

6.3.14.1. Justify the dosing to be used.